RULES AND REGULATIONS
FOR
HEALTH MAINTENANCE ORGANIZATIONS
IN ARKANSAS

ARKANSAS DEPARTMENT OF HEALTH

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COMPILED BY: DIVISION OF HEALTH FACILITY SERVICES

ARKANSAS DEPARTMENT OF HEALTH

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SECTION I. AUTHORITY.

The following Rules and Regulations for Health Maintenance Organizations in Arkansas are duly adopted and promulgated by the Arkansas Department of Health pursuant to the authority expressly conferred by the laws of the State of Arkansas in Act 454 of 1975.

SECTION II. PURPOSE.

These Rules and Regulations have been prepared for the purpose of establishing a criterion for minimum standards for licensure and operation of Health Maintenance Organizations in Arkansas that is consistent with current trends in patient care practices. By necessity they are of a regulatory nature, but are considered to be practical minimum design standards for these entities/facilities. These standards are not static and are subject to periodic revisions in the future as new knowledge and changes in patient care trends become apparent. However, it is expected that Health Maintenance Organizations will exceed these minimum requirements and that they will not be dependent upon future revisions in these standards as a necessary prerequisite for improved services. Health Maintenance Organizations have a strong moral responsibility for providing a progressive preventive health program which assures that adequate medical care is available and acceptable to all Enrollees.

These Rules and Regulations apply to certified Health Maintenance Organizations, as well as to applicants for a Health Maintenance Organization Certificate of Authority, and are promulgated to carry out Act 454 and to facilitate the full and uniform implementation, enforcement, and intent of the Act.

These Rules and Regulations explain the requirements a Health Maintenance Organization applicant must satisfy in order for the Arkansas Department of Health to certify to the Arkansas Insurance Department that the applicant's proposed plan of operation meets Arkansas Department of Health requirements.

These Rules and Regulations are adopted in the best interest of the public health, safety, and welfare. Compliance with these Rules and Regulations in no way conveys assurance of the quality of patient care, but rather provides the basic framework of capabilities required from which quality patient care may evolve.

Persons in the process of developing a Health Maintenance Organization shall periodically inform the Department of their developmental activities and make use of Department technical advice and assistance.

SECTION III. DEFINITIONS.

As used in these Rules and Regulations, unless the content otherwise requires, the words and terms defined in Section III inclusive, have the meanings ascribed to them.

A. **Act.** Arkansas Act 454 of 1975, as amended.

B. **Administrator.** The person responsible for the management of the Health Maintenance

Organization (HMO).

C. **Case Management.** An activity which assists individuals in gaining and coordinating access to necessary care and services appropriate to the needs of the individual. It is the facilitation of health services including either medical or ancillary health care resources for efficient and medically appropriate ends for enrolled members. The activity is designed to achieve the optimal patient outcome in the most cost-effective manner.

D. **Certificate of Authority.** A document issued by the Commissioner of the Arkansas Insurance Department permitting one to establish, maintain, and operate an HMO.

E. **Commissioner.** The Commissioner of the Arkansas Insurance Department.

F. **Consumer.** Solely for the purpose of the composition of the Governing Body/Oversight Committee, is any person other than a person (i)whose occupation involves, or before retirement involved, the administration of health activities or the providing of Health Care Services, (ii) who is, or ever was, employed by a health care facility as a licensed Health Professional, or (iii) who has, or ever had, a direct, substantial financial or managerial interest in the rendering of Health Care Services other than the payment of a reasonable expense reimbursement or compensation as a member of the board of an HMO.

G. **Credentials.** Certificates, diplomas, licenses, or other written documentation which establish proof of training, education, and experience in a field of expertise.

H. **Department.** The Arkansas Department of Health.

I. **Director.** The Director of the Arkansas Department of Health.

J. **Emergency Health Care Services.** Those Health Care Services which shall be available on a twenty-four (24) hours per day, seven (7) days per week basis to evaluate and treat medical conditions of a recent onset and severity, including, but not limited to, severe pain that would lead a prudent lay person, possessing an average knowledge of medicine and health, to believe that his or her condition, sickness, or injury is of such a nature that failure to get immediate medical care could result in (i) placing the patient's health in serious jeopardy; (ii) serious impairment to bodily functions; or (iii) serious dysfunction of any bodily organ or part.

K. **Enrollee.** An individual who is contractually entitled to receive covered Health Care Services from an HMO.

L. **Evidence of Coverage.** Any certificate, agreement, contract, identification card, or document issued to an Enrollee setting out the coverage to which he/she is entitled.

M. **Health Care Plan.** Any arrangement whereby any person undertakes to provide, arrange for, pay for, or reimburse any part of the cost of any Health Care Services, and at least part of such arrangement consists of arranging for or the provision of Health Care Services, as distinguished from mere indemnification against the cost of such services, on a prepaid basis

through insurance or otherwise.

N. **Health Care Services.** Any services included in the furnishing to any individual of medical or dental care, or hospitalization or incident to the furnishing of such care or hospitalization, as well as the furnishing to any person of any and all other services or goods for the purpose of preventing, alleviating, curing, or healing human illness or injury.

O. **Health Maintenance Organization (HMO).** Any person who undertakes to provide or arrange for one or more Health Care Plans under the Act.

P. **Health Professional.** Individuals engaged in the delivery of Health Care Services as are or may be designated under U.S. Public Law 93-222, same being the Health Maintenance Organization Act of 1973 or any amendment thereto or regulation adopted thereunder.

Q. **Hospital.** As defined in the currently certified Rules and Regulations for Hospitals and Related Institutions in Arkansas as promulgated by the Arkansas Department of Health.

R. **Inpatient Medical Care.** Shall include, but not be limited to medical and surgical care received in a hospital or skilled nursing environment.

S. **Limited Benefit HMO.** An HMO that elects to provide or arrange for the provisions of one (1) Health Care Service (e.g. dental, mental health, vision, etc.) to its Enrollees. The limited benefit shall be the only type of benefit offered to Enrollees under its Health Care Plan. An HMO certified in this category shall comply with all applicable provisions of these Rules and Regulations.

T. **Medical Director.** A physician (M.D. or D.O.) licensed to practice in the State of Arkansas. The Medical Director shall provide medical direction of the HMO's health care activities and consultation for and medical supervision of the medical staff of a Staff Model HMO.

U. **Outpatient Services.** Those covered services which may be rendered in, but are not limited to, clinics, home health services, hospices, kidney dialysis centers, private offices, pharmacies, and hospital-based outpatient services, as a minimum, and may also include, but are not limited to outpatient surgery centers and radiation therapy centers.

V. **Peer Review.** A review of the decisions and actions by one's peers within the organizational structure of the HMO.

W. **Person.** Any natural or artificial person including, but not limited to individuals, partnerships, associations, trusts, or corporations.

X. **Pharmacy.** A facility which possesses the appropriate permit from the Arkansas State Board of Pharmacy.

Y. **Physical Plant.** The physical building, equipment, and fixtures of a Staff Model HMO. It shall include, but not be limited to environment, electrical services, plumbing services, water supply and disposal, infection control, and waste disposal.

Z. **Preventive Health Services.** Services designed to maintain an individual in optimum health and to prevent unnecessary injury, illness, or disability.

AA **Primary Care Physician.** A physician who supervises, coordinates, and provides initial and basic care to Enrollees; initiates their referral for specialty care; and maintains the continuity of patient care. The care of episodic illness alone does not constitute the role of a Primary Care Physician.

BB. **Private Review Agency.** Any entity certified by the Department under Act 537 of 1989 performing utilization review that is either affiliated with, under contract with, or acting on behalf of an Arkansas business entity or a third party that provides or administers hospital and medical benefits to citizens of Arkansas including an HMO or any entity offering health insurance policies, contracts, or benefits in this State including a health insurer, non-profit health service plan, health insurance organization, preferred Provider organization, or managed care organization.

CC. **Provider.** Any person who is licensed in this State to furnish Health Care Services as a Health Professional.

DD. **Quality Assurance Systems.** The planned and systematic management actions which assure the consistent rendering of high quality Health Care Services through the use of monitoring techniques.

EE. **Retrospective Review.** A mechanism to review medical necessity and appropriateness of medical services through compilation and analysis of data after medical care is rendered which includes, but is not limited to the comparison of Provider practice patterns with parameters established by the utilization review committee, recommendations of changes in Provider practice patterns based on analysis and review, and analyzation of care to Enrollees.

FF. **Service Area.** The geographic area as defined by county boundaries authorized by the Certificate of Authority.

GG. **Staff Model HMO.** An HMO that provides any of its Health Care Services through physicians and other Health Professional who work in centralized health centers as salaried or paid employees (staff) of the HMO and where the Health Care Service is provided at a health center owned or leased by the HMO. It shall include a described Physical Plant.

HH. **Utilization Review Plan.** A system for the formal assessment of medical necessity, efficiency, and/or appropriateness of Health Care Services and treatment plans on a prospective, concurrent, or retrospective basis.

SECTION IV. LICENSURE.

No person shall perform any of the services or procedures or sell or dispense any goods or devices in the field of the healing arts for which a license is required under the laws of the State of Arkansas unless such person holds a valid license authorizing him or her to perform said procedures or render

such services or dispense such good or devices. A valid license is a license from Arkansas or from the state where the services are provided. Except for ambulatory care facilities not required to be licensed by the State of Arkansas, the HMO shall utilize only health care facilities that hold a valid license or are certified as a Provider or supplier for Medicare, Medicaid, or CLIA (Clinical Laboratory Improvement Amendments of 1988).

SECTION V. GENERAL REQUIREMENTS

A. The HMO shall provide and/or arrange for the provision of Health Care Services which assure the Enrollees adequate medical care which is available, accessible, and continuous in accordance with the Enrollee's Plan. Assurances of availability, accessibility and continuity shall demonstrate the following:

1. Health Care Services for which Enrollees have contracted shall be provided or arranged for by the HMO;

2. Facilities and personnel, both professional and non-professional, adequate (within generally accepted norms) to make these Health Care Services available to Enrollees can and shall be secured and maintained.

3. These Health Care Services shall be provided at hours convenient to and adequate to meet the needs of Enrollees, including provision or arrangement for 24-hour emergency service. The average waiting time for appointments or to receive services shall be reasonable;

4. The location of facilities and proximity shall enhance accessibility of service to the reasonably anticipated Enrollees, including aged and persons with disabilities;

5. Owned facilities and/or leased facilities of a Staff Model HMO shall not present architectural barriers to the aged or to persons with disabilities;

6. For initial Staff Model HMO applicants, plans and resources, both current and reasonably anticipated, drawings and specifications (if applicable), and other materials shall be required, in addition to other requirements of these Rules and Regulations;

7. Continuity of service to Enrollees shall be enhanced by provision of a means for ensuring that Enrollees receive the proper level and type of care and that the provision of services is coordinated both within and outside the HMO.

B. There shall be a progressive preventive health program which shall be developed according to the prevailing health factors predominant in the Enrollee population. This program shall include, but not be limited to health evaluation, education, and immunization. The program shall be designed to prevent illness and disease and to improve the general health of the HMO Enrollees.

SECTION VI. ISSUANCE OF CERTIFICATE OF AUTHORITY.

A. Upon receipt of an application for issuance of a Certificate of Authority, the Commissioner shall transmit copies of the application and accompanying documents to the Director. The Director shall determine whether the applicant meets the requirements with respect to Health Care Services to be furnished for receipt of a Certificate of Authority.

B. If the Director determines that the HMO does not meet such requirements, he shall specify in what respects it is deficient. A request shall be sent in writing to the applicant stating specifically what information is needed. A copy of the request shall be sent to the Commissioner. However, the Director shall not certify to the Commissioner that such requirements are not met unless the proposed HMO has been given the opportunity to comment on the proposed findings of the deficiency or to furnish the required information. If requested by the proposed HMO, the Director shall hold a hearing on the finding of deficiency.

C. These requirements shall also apply to applications and/or requests for amendments to the Certificate of Authority of an operational HMO.

SECTION VII. CONTENT OF APPLICATION FOR CERTIFICATE OF AUTHORITY.

A. No person shall operate an HMO without first obtaining a Certificate of Authority from the Commissioner.

B. In addition to the requirements of the Commissioner, an application for a Certificate of Authority shall include, at a minimum:

1. Copies of the basic organizational documents such as certificates of incorporation, bylaws, rules, articles of association, partnership agreement, trust agreement, or other applicable documents and agreements relating to the conduct of the internal affairs of the applicant and all amendments thereto;

2. A list of the names and addresses and official positions of the members of the board of directors, officers, controlling persons, owners, or partners, the Medical Director, and the Administrator of the proposed HMO;

3. A curriculum vita and/or resume of the Administrator and the Medical Director;

4. A detailed description of the proposed HMO′s potential ability to assure both the availability and accessibility of adequate personnel and facilities to serve Enrollees in a manner enhancing availability, accessibility, and continuity;

5. A description of the service area of the proposed HMO (geographic boundaries and demographic data);

6. Information regarding proposed administrative site locations and hours of operation;

7. Listing of Providers who have signed contracts and/or letters of intent to contract;

8. A list of Health Care Services to be provided or arranged for by the HMO;

9. A copy of the applicant's proposed form of evidence of coverage to be issued to Enrollees, setting forth the HMO's contractual obligation to provide and/or arrange for the provision of Health Care Services;

10. A form of the applicant's Provider contracts;

11. A detailed description of the applicant's program for Preventive Health Services;

12. A detailed description of the applicant's proposed grievance resolution system whereby the complaints of the Enrollees may be acted upon promptly and in a reasonable manner;

13. A detailed description of the applicant's ongoing quality assurance/improvement program;

14. A detailed description of the applicant's capability to collect and analyze necessary data relating to the utilization of Health Care Services;

15. Job description for the Administrator, Medical Director, and senior personnel;

16. A procedure for the referral of Enrollees to non participating Providers, when not otherwise available or appropriate under the circumstances;

17. A copy of the written procedures for provision and payment of Emergency Health Care Services;

18. A detailed description of how medical records will be maintained for administrative purposes within the HMO.

19. For a Staff Model HMO, an organizational chart demonstrating the delegation of authority and control of the Health Care Services delivery system, from the highest authority to the physician, with support documentation exhibiting all personnel at each level of authority have requisite expertise for their particular area of authority;

20. For a Staff Model HMO, a statement of the number and qualifications of all support staff employed directly by the HMO (i.e. registered nurses, practical nurses, mid-level practitioners, medical social service personnel, medical records personnel, pharmacists, physical therapists, speech pathologists, physicians, etc.);

21. Any other pertinent information, as designated by the Director, and as required by other sections of these Rules and Regulations.

SECTION VIII. ORGANIZATION.

A. The Health Maintenance Organization shall be organized in a manner which demonstrates that it has the legal qualifications, authority, and ability to assure that Health Care Services will be provided. For covered services, the HMO shall provide and/or arrange for the

provision of:

1. Emergency Health Care Services;
2. Inpatient Hospital and medical-surgical care;
3. Outpatient services;
4. Preventive Health Services and health education services.

These services are provided for the purposes of preventing, alleviating, curing, or healing human illness or injury.

B. Those persons legally responsible for the operation of the HMO shall provide the following;

1. A copy of the agreement, contract, or policy which the HMO proposes to issue to Enrollees which describes the scope of Health Care Services it renders, as permitted by law, to Enrollees either directly by a Provider staff or through arrangement with other;
2. The names of all Providers (giving their license number), business address, specialty where applicable (board certification or eligibility), and medical or Hospital staff privileges at Hospitals used, or by which the HMO has a contractual arrangement, and the maintenance of a listing of this information;
3. The appointment of a full-time Administrator;
4. The appointment of a Medical Director. The position may be either full-time or part-time in accordance with the demands of the office. The Medical Director may serve as the chief of the medical staff of a Staff Model HMO. A Staff Model HMO shall formulate medical staff bylaws, rules, regulations, or other appropriate means to include provisions for the delivery of Health Care Services by physicians and Providers, licensed or duly authorized to practice in the State of Arkansas. Other Providers, as required, to support the medical staff shall be available in order to assure that the Enrollee receives Health Care Services with continuity and without unreasonable periods of delay;
5. An ongoing quality assurance/improvement program;
6. Assurance that files are maintained to include current contracts for all participating physicians and Providers.

C. Those persons legally responsible for the overall operation of the HMO shall have responsibilities which include, but are not limited to:

1. Adoption and enforcement of all policies governing the HMO's management of Health Care Services delivery, quality assurance/improvement, and utilization review programs including at least annual meetings for the purpose of evaluation and improvement of Health Care Services of the HMO and to react to recommendations

and/or findings of the quality assurance/improvement committee. Records, as well as minutes of meetings shall be maintained;

2. Authority to employ and terminate the Administrator and Medical Director;

3. Adoption of the HMO's procedures for maintenance and control of all books, records, and audits which are related to its operation;

4. Assurance that the HMO's Administrator is performing the duties of that position;

5. Assurance that the HMO's Medical Director is performing the duties of that position and in a manner that results in operation of a quality assurance/improvement program that is effective and otherwise in compliance with the requirements of these Rules and Regulations;

6. Adoption of policies and procedures regarding the delivery of Health Care Services to Enrollees;

7. Provision of reasonable access by the Medical Director; and

8. Assurance that the HMO complies with applicable laws and regulations.

D. The HMO shall be organized to accomplish its stated mission which shall include, as a minimum, provision of or arranging for the provision of Health Care Services.

E. The HMO shall possess organizational and administrative capacity to provide or arrange for the provision of Health Care Services and the ability to monitor the provision of such services.

SECTION IX. GOVERNING BODY.

A. The governing body and/or oversight committee of any HMO shall include at least one (1) physician, one (1) dentist, one (1) pharmacist, and one (1) nurse, all of whom shall be licensed in the State of Arkansas; and one (1) Enrollee and one (1) Consumer. These members of the governing body and/or oversight committee shall also be residents of the State of Arkansas.

B. Such governing body/oversight committee shall establish a mechanism to afford Enrollees an opportunity to participate in matters of policy operation through the establishment of advisory panels, by the use of advisory referenda on major policy decisions, or through the use of other mechanisms approved by the Director.

SECTION X. FACILITIES AND ENVIRONMENT.

A. **Facilities owned and/or operated by the Health Maintenance Organization.**

1. There shall be a described Physical Plant for all such facilities.
2. There shall be sufficient equipment and supplies for examination, diagnosis, and treatment in accordance with Enrollee contracts.
3. There shall be a listing which shall include the name and location of the facility or facilities other than the main service location, if any, enumerating the services offered at each facility location and the service hours, including evenings and holidays. The lists shall be available to the Director and the Enrollees.
4. Such facilities shall comply with the applicable parts of the *Physical Environment Section, Outpatient Facilities,* of the currently certified Rules and Regulations for Hospitals and Related Institutions, as promulgated by the Department.
5. The Physical Plant shall comply with all applicable provisions of state and local fire safety, plumbing, and building codes.

B. **Contracted Providers of Services**. If all or part of the HMO services are to be performed by contract with Providers of service, the following shall apply:

1. All Providers of Service shall be licensed or registered according to applicable state and local laws;
2. All contracted services shall be clearly identifiable.

Any major changes in the scope of services to be offered to Enrollees shall be approved by the Director. Notification of changes shall be forwarded to the Director at least one month in advance of their anticipated implementation.

SECTION XI. SERVICES.

The requirements of this Section are applicable to the categories of services listed as available under the Health Care Plan. The HMO may wish to provide such services directly or arrange for their provision according to the specific requirements of the Plan. Outside resources with which a Staff Model HMO contracts shall be approved by the Director.

A. **Emergency Health Care Services.** Policies and procedures shall be developed pertaining to Emergency Health Care Services to include after-office-hour Provider services. Such policies shall include the conditions for which an Enrollee should seek immediate assistance prior to contacting the HMO, in order to minimize the time for treatment in critical and/or urgent situations. All Enrollees shall have access to an HMO staff or an HMO contracted physician licensed to practice in the State of Arkansas. A physician shall be available at least by telephone on a twenty-four (24) hour basis, seven (7) days a week to respond to urgent calls from Enrollees. Emergency Health Care Services shall be available without restrictions as to where the services are provided. Physicians and Providers of care which employ triage nurses and/or mid-level practitioners to assess the health care needs of Enrollees shall also have policies in effect which describe the exact duties of the involved

professionals.

B. **Primary Care Physician Services.** Policies and procedures shall be developed pertaining to Primary Care Physician Services. There shall be a sufficient number of participating Primary Care Physicians to meet the needs of the enrolled membership. Such policies shall include requirements that an adequate number of Primary Care Physicians have admitting privileges and/or a referral arrangement at one or more participating Hospitals located within the HMO's Service Area to assure that necessary admissions are made. Such policies shall also meet the above requirements for the provision of Emergency Health Care Services and after hour access. The method by which Enrollees may secure Health Care Services after hours shall be clearly communicated in writing to Enrollees.

C. **Inpatient Hospital and Medical Care.** An agreement with at least one Hospital shall be obtained by the HMO to assure immediate access to covered Hospital Health Care Services as needed. In counties where there is no licensed Hospital, the Director will give consideration to contracted facilities within the Service Area of the HMO to meet requirements of availability, accessibility, and continuity. Inpatient Hospital care shall be available and accessible twenty-four (24) hours a day, seven (7) days a week within the HMO's defined geographical Service Area. Hospitals which provide services shall be currently licensed by the Arkansas Department of Health.

D. **Outpatient Services.** Ambulatory Outpatient Services shall be provided. These services shall, as a minimum, include an ongoing preventive health program.

E. **Diagnostic Laboratory Services.** Each HMO shall have available diagnostic laboratory services commensurate with the needs of its Enrollees. Each laboratory shall possess a current Clinical Laboratory Improvement Amendments of 1988 (CLIA) certificate authorizing the performance of testing. The use of outside reference laboratories and/or accredited laboratories shall meet this requirement. All laboratory services shall meet the non-emergent, urgent, and emergency needs of Enrollees. Reference laboratory specimen services shall be convenient to Provider physicians through the strategic location of drawing stations or through a courier service which is under the management of the reference laboratory. Staff Model HMOs shall provide and/or arrange for the provision of laboratory services in clinical chemistry, pathology, microbiology, hematology, serology, and urinalysis.

F. **Diagnostic Imaging.** Diagnostic imaging services shall be available and accessible to all Enrollees. Those procedures that require the injection/ingestion of radiopaque chemicals shall be performed only under the supervision of physicians qualified to perform such procedures. Diagnostic imaging machines shall be registered and inspected in accordance with Arkansas State law. Personnel who work with imaging machines shall comply with State law regarding monitoring.

G. **Pharmacy Services.** Pharmacy services shall be available and accessible within the Service

Area of the HMO to Enrollees. Pharmacy services shall be offered directly by the HMO or through contracts with pharmacies licensed by the Arkansas State Board of Pharmacy. The plan of pharmacy services provided by the HMO shall be under the supervision of the Director of Pharmacy Services and shall assure quality of and accessibility to pharmacy services. The plan shall include an acceptable drug utilization review and claims processing system. If a Staff Model HMO has a pharmacy department, a licensed pharmacist with a permit from the Arkansas State Board of Pharmacy shall be employed to administer the pharmacy in accordance with all State and Federal laws regarding drugs and drug control. The pharmacy director shall develop policies and procedures for administration of the pharmacy department. There shall be a committee composed of physician(s), pharmacist(s), and other professionals needed to regularly review the quality of pharmacy services of the HMO.

1. The committee shall be responsible for assuring that drug utilization review is performed on a regular basis, but no less frequently than quarterly.
2. The committee shall assure that contracting pharmacies maintain medication profiles on the Enrollees and utilize such profiles to detect inappropriate medication use.
3. The committee shall make recommendations on polices under which pharmacists provide pharmacy care to Enrollees.

H. **Home Health Care.** If home health care is covered, it shall be available and accessible within the Service Area of the HMO to Enrollees. This service may be offered through home health agencies and their branches or sub-offices, which are licensed by the State. Home Health care may be provided directly by the HMO or through contracts. Hospices shall be appropriately licensed.

I. **Nursing Home Care.** If nursing home care is covered, it shall be available and accessible within the Service Area to the enrolled population by one or a combination of the following facilities:

1. A skilled nursing home that is licensed by the State and certified by Medicare or Medicaid or both;
2. A Hospital with swing-beds that is licensed by the State and certified by Medicare;
3. A Hospital licensed by the State, a distinct part of which is a skilled nursing facility.

Nursing home care may be provided by facilities owned and operated by the HMO or by contract.

J. **Other Services.** Other covered services shall be in accordance with those specified in the Health Care Plan. If Health Care Services such as dental, podiatric, nutrition/dietary, vision, hearing, speech, durable medical equipment, mental health, drug dependency, chiropractic care, or others not listed are offered, they shall be provided directly by the HMO or through

contracts with Providers or physicians who hold a valid license or are otherwise allowed to practice in the State of Arkansas. Such services shall be of sufficient number and locations and as approved by the Director to be readily available and accessible to Enrollees.

SECTION XII. PROFESSIONAL STAFFING.

A. An HMO shall have sufficient numbers of physicians and other Health Professionals, either as employees or by contract, to adequately cover the health care needs of Enrollees.

B. There shall be established a credentials committee charged with the responsibility of reviewing each physician and other Health Professionals, as established by the policies and procedures of the HMO, to determine that the Health Professionals are properly credentialed in Arkansas. This committee shall conduct reviews of said personnel at intervals necessary to assure appropriate licensure and certification.

C. In addition to other requirements, the Medical Director of the HMO shall be involved in the implementation of protocols for the credentials committee, protocols for quality assurance, and programs for continuing education for Health Professionals.

D. The HMO shall define procedures for taking corrective action against any Provider whose conduct is detrimental to public safety or the delivery of care, or disruptive to the operation of the HMO.

SECTION XIII. MEDICAL RECORDS.

A. The HMO shall maintain or cause the Provider to maintain an active record for each Enrollee who receives Health Care Services. This record shall be kept current, complete, legible, and available to the medical and administrative staff of the HMO and to the Department's representatives. The HMO shall have policies and procedures, as related to medical records, for the review of physicians and other Providers. The policies and procedures shall address, at a minimum, the retention, security, storage, confidentiality, transfer, release, and destruction of medical record information.

B. Each medical record shall contain sufficient information and data to support diagnosis, plan of treatment, and other pertinent medical information such as medical history, progress notes, and other related reports.

C. The HMO shall require that each entry be indelibly added to the Enrollee's record, dated, and signed or initialed by the person making the entry. The HMO shall require each Provider site to have a means of identifying the name and professional title of the individual who makes the entry.

D. The medical record for each Enrollee who has had a routine, scheduled appointment with one of the HMO's Providers shall include basic information collected; as a minimum, identification of the Enrollee, patient history, known past surgical procedures, known past and current diagnoses and problems, and known allergies and untoward reactions to drugs.

E. The HMO shall require that the medical records for each Enrollee who receives Health Care Services include the following information regarding each episode of care:

1. Reason for the encounter;
2. Evidence of the Provider's assessment of the Enrollee's health problems;
3. Current diagnosis of the Enrollee, including the results of any diagnostic testing;
4. Plan of treatment, including any therapies and health education; and
5. Medical history relevant to the current episode of care if not available as Part D above.

F. The HMO shall require each Provider site to document that all outcomes of ancillary reports, such as laboratory tests and x-rays have been reviewed by the Provider who requested the reports. The HMO shall require each Provider site to document that follow-up actions have been taken regarding report results that are deemed significant by the Provider who requested the report.

G. Arrangements shall be made for the sharing of pertinent medical records among Providers participating in the HMO and for maintenance by the HMO when needed for committee reviews. In all cases, the confidentiality of the record shall be assured.

SECTION XIV. ENROLLEE RIGHTS.

A Health Maintenance Organization shall develop and adhere to written policies and procedures informing Enrollees of at least the following rights;

A. An Enrollee has the right to timely and effective redress of grievances through a system established by the HMO in a complaint/grievance program.

B. An Enrollee has the right to obtain current information concerning a diagnosis, treatment, and prognosis from a physician or other Provider in terms the Enrollee can be reasonably expected to understand. When it is not advisable to give such information to the Enrollee, this information shall be made available to an appropriate person on the Enrollee's behalf;

C. An Enrollee has the right to be given the name, professional title, and function of any personnel providing Health Care Services to him/her;

D. An Enrollee has the right to give his/her informed consent before the start of any surgical procedure or treatment;

E. An Enrollee has the right to refuse any medications, treatment, or other procedure offered to him/her by the HMO or its Providers to the extent provided by law and to be informed by a physician of the medical consequences of the Enrollee's refusal of any medications, treatments, or procedures;

F. An Enrollee has the right to obtain Emergency Health Care Services without unnecessary

delay;

G. An Enrollee has the right to have all records pertaining to his/her medical care treated as confidential unless disclosure is otherwise permitted by law;

H. An Enrollee has the right to information in his/her medical records, consistent with state law. Nothing in these regulations shall prohibit a Provider from charging for copies of the information, also consistent with state law;

I. An Enrollee has the right to be advised if a health care facility or any of the Providers participating in his/her care propose to engage in or perform human experimentation or research affecting his/her care or treatment. An Enrollee or legally responsible party on his/her behalf may, at any time, refuse to participate or to continue in any experimentation or research program to which he/she had previously given informed consent;

J. An Enrollee has the right to be informed of these rights listed in this Section; and

K. No HMO may, in any event, cancel or refuse to renew an Enrollee solely on the basis of the health of an Enrollee.

SECTION XV. STATISTICAL INFORMATION.

There shall be a procedure for the HMO to compile, develop, evaluate, and report, as may be requested and in the form indicated by the Director, statistics relating to the cost of operation, the pattern of utilization of services, and the availability and accessibility of services. Sufficient information shall be maintained to support continuity and adequate quality of care to Enrollees.

A. Each membership file shall include, as a minimum:

1. Name of the individual and if other than the individual, also the name and address of the Enrollee;
2. Individual's identification number;
3. Date of birth;
4. Sex;
5. Effective date;
6. Termination date and reason(s);
7. Date of most recent verification of information; and
8. Such other information as the Commissioner and Director may require.

B. Service area demographic characteristics which include the age, sex, and the geographic residence of Enrollees, and the number of Enrollees terminated during each one year period shall be available to the Department;

C. The HMO shall compile the number of medical services encounters, the number of Inpatient

Medical Care encounters, and the number of direct ambulatory encounters for Enrollees for each one year period. The information shall be available to the Department as may be requested, and in the form indicated by the Director.

1. Medical services shall mean those services provided for the prevention, diagnosis, treatment, and rehabilitation of physical illness by Health Professionals.

2. Direct ambulatory encounters shall mean face-to-face contacts between patients not confined to a health care institution and a Health Professional employed actively and directly by the HMO, or by contract, who exercises independent judgment in the care and provision of Health Care Services to the patient. The term Aindependent@ is used to distinguish between Health Professionals who assume major responsibility for the care of individual Enrollees and all other personnel who assist in providing that care.

D. Enrollee surveys and comments, as well as other materials shall be made available to the Director;

E. Each HMO shall annually, on or before the first day of March, file a report, verified by at least two principal officers of the HMO, with the Commissioner, with a copy to the Director, covering the previous calendar year. It shall include a summary of the statistical information required. Interim reports may be required by the Director.

SECTION XVI. COMPLAINT/GRIEVANCE SYSTEM.

A. Each HMO shall establish and maintain a complaint/grievance system approved by the Commissioner, after consultation with the Director, to provide reasonable procedures for the resolution of complaints and grievances initiated by Enrollees concerning Health Care Services.

B. Each HMO shall provide a designated position/title with a designated telephone number and address for receiving oral and written complaints and inquiries concerning complaints and for assisting the Enrollee.

1. Oral complaints and inquiries regarding complaints shall be entered into a written or automated record.

2. Enrollees with complaints which are not resolved shall be informed of the written grievance procedure. Any oral complaint which cannot be resolved informally shall be presented in writing before it can be considered a formal grievance.

C. Each HMO shall have a written grievance procedure for prompt and effective resolution of Enrollee grievances. The grievance procedure shall include, as a minimum, assisting the Enrollee with filing the grievance and the following elements:

1. There shall be an initial level of investigation and review of any grievance;

2. The initial review shall provide the opportunity for the Enrollee and any other party

of interest to present data pertinent to the grievance;

3. The decision of the initial review shall be binding unless the Enrollee appeals the decision in writing;

4. The Enrollee shall be notified in writing of the decisions. If the outcome is adverse to the Enrollee, the written notice shall include specific findings related to the grievance, the reason(s) for denial, and the right of the Enrollee to appeal to a second level.

D. An Enrollee shall have the right to appeal a decision of the initial review to a second level review committee.

1. The second level of review shall be conducted by a committee established by the HMO.

2. The second level review committee shall have written procedures for investigating grievances and for utilizing informed consultants to resolve grievances.

3. The Enrollee shall be notified in writing of the decision of the second level review. If the outcome is adverse to the Enrollee, the written notice shall include the specific findings related to the decision, the reason(s) for denial and the right of the Enrollee to appeal the decisions of the second level review committee to the Commissioner of Director.

E. The HMO shall specify time limits for receipt and disposition of grievances at each level of review. The time frame for each level shall not exceed thirty (30) days unless the HMO provides documentation for justification of a longer time frame.

F. The HMO shall include a description of the complaint/grievance system in the Enrollee Evidence of Coverage.

G. At any stage of the grievance process, at the request of the Enrollee, the HMO may appoint a member of its staff, who has no direct involvement in the case, to assist the Enrollee. An Enrollee presenting a grievance shall be specifically notified of his/her right to have such a staff member appointed for assistance.

H. Each HMO shall submit to the Commissioner and the Director an annual report which shall include:

1. A description of the procedures of such grievance/appeals system;

2. The total number of grievances/appeals handled through such grievance/appeals system and a compilation of the causes underlying those filed;

3. For a Staff Model HMO, the number, amount, and disposition of malpractice claims settled during the year by the HMO and any of the Providers utilized by it;

4. A summary of the disposition of grievances/appeals; (the copy to the Director shall

also include a summary of the processing times as an addendum), and

5. Any such other information as reasonably required by the Commissioner or Director pursuant to these Rules and Regulations.

I. The Commissioner or Director may examine such grievance/appeals system subject to limitations concerning medical records of Enrollees.

J. The Director shall investigate each complaint filed with the Department concerning Health Care Services of an HMO or its Providers.

SECTION XVII. UTILIZATION REVIEW.

A. Each HMO shall develop a Utilization Review Plan that includes:

1. A description of review standards and procedures to be used in evaluating proposed, ongoing, or delivered hospital and outpatient medical services;

2. The provisions by which patients, physicians, or hospitals may seek reconsideration or appeal of adverse decisions;

3. The type, qualifications, and oversight of the personnel performing utilization review and case management;

4. The policies and procedures to insure that a utilization review representative is reasonably accessible to patients and Providers five (5) days a week during normal business hours in Arkansas;

5. The policies and procedures to insure that all applicable state and federal laws to protect the confidentiality of individual medical records are followed;

6. Compliance with all relevant provisions of rules and regulations promulgated pursuant to Act 537 of 1989.

B. If a private review agent performs the utilization review, that entity shall meet the requirements of Act 537 of 1989 and rules and regulations promulgated pursuant to same Act.

SECTION XVIII. QUALITY ASSURANCE/IMPROVEMENT SYSTEMS.

A. Each HMO shall develop and implement a quality assurance/improvement (QA/I) program subject to approval by the Director. The program shall include a method for analyzing the outcomes of health care, peer review, the collection of health care data, and appropriate recommendations for remedial action. It shall include organizational arrangements and ongoing procedures for the identification, evaluation, intervention, and follow-up of potential and actual problems in health care administration and delivery to Enrollees.

B. The QA/I organizational arrangements and ongoing procedures shall be fully described in written form, and a summary provided to all members of the governing body, Providers, and

staff, and made available, upon request, to Enrollees of the HMO. This written program shall be clearly defined and transmitted to all individuals involved in the QA/I program and shall include, but not be limited to, the following:

1. Provision for necessary staff to implement the program and evaluate the effectiveness of the program;
2. Formation of a QA/I committee responsible for QA/I activities and utilization review activities;
3. Requirements of responsibility for all QA/I activities conducted by the HMO or for activities delegated to another entity;
4. Accountability of the committee to the Administrator and to the persons legally responsible for the operation of the HMO including written and oral reports related to the continuity and effectiveness of the program and any findings of the committee, with recommended actions as needed to improve the program.

C. As a minimum, studies undertaken, results, subsequent actions, and aggregate data on utilization and quality of services, rendered to Enrollees shall be compiled.

D. There shall be participation, supervised by the Medical Director, of Providers and support staff appropriate to the current QA/I studies.

E. Minutes or records of the QA/I committee shall be maintained.

F. The QA/I procedures shall include defined methods for the identification and selection of clinical and administrative problems. Input for problem identification shall come from multiple sources including, but not limited to, medical chart reviews, Enrollee complaints, utilization review, Enrollee assessment audits, and HMO services. Methods shall be established by which potential problems are selected and scheduled for further study.

G. Each HMO shall document the manner by which it examines actual and potential problems in health care administration and delivery.

H. The QA/I activities shall include the development of recommendations that are timely and appropriate for problems that are identified, and the HMO shall demonstrate an operational mechanism for responding to those problems.

I. There shall be evidence of adequate follow-up on recommendations and such follow-up shall meet the standards of the currently approved QA/I plan of the HMO.

J. Review of quality of care shall not be limited to technical aspects of care alone, but shall also include availability, accessibility, and continuity of care provided to Enrollees.

K. The QA/I program shall include written guidelines which set forth the procedures for remedial actions when problems related to quality of care are identified. The guidelines shall include:

1. A listing of the types of problems which require remedial action;
2. Specific remedial actions required, with time frames within which Providers of health care must comply with such remedial actions;
3. The procedures used to assess the effectiveness of any remedial action;
4. Procedures utilized by the HMO if remedial actions are not implemented as required, to include specific procedures for terminating an affiliation with a physician or other health care Provider.

L. All records and minutes shall be available for review by Department representatives.

SECTION XIX. EXTERNAL QUALITY ASSURANCE/IMPROVEMENT ASSESSMENT.

A. When the Department determines that a significant quality problem exists that is not being addressed internally, that HMO shall have an external QA/I assessment performed. Such external assessment shall study the quality of care being provided to Enrollees and the effectiveness of the QA/I program established by the HMO.

B. The assessment shall be conducted by a person or persons hired by the HMO and not involved in the operation or direction of the HMO or in the delivery of Health Care Services to its Enrollees.

C. The person or persons hired shall be an individual or organization with recognized experience in the appraisal of medical practice and quality assurance in an HMO setting.

D. The person or persons hired shall be approved by the Director and shall report at frequent intervals to Department representatives during the assessment period.

E. The person or persons hired shall issue a written report of findings to the HMO's governing body. A copy of this report shall be submitted to the Director within ten (10) business days of its receipt by the HMO.

SECTION XX. RECORDS MAINTENANCE.

A. Each HMO shall maintain all of its books, records, files, procedures, minutes, and any other required documentation to support compliance with these Rules and Regulations at, and under the control of, its principal place of doing business in Arkansas.

B. All such records shall be maintained for a period corresponding to the time interval between each onsite review of the quality of care of the HMO by the Department.

SECTION XXI. ONSITE QUALITY OF CARE REVIEWS.

A. The Director shall conduct an examination concerning the quality and appropriateness of covered Health Care Services provided and/or arranged for by the HMO as often as is deemed necessary for the protection of the interests of the citizens of this State and for the

protection of Enrollees of each HMO. The examination shall not be less frequent than once every three (3) years. Such examinations shall be subsequent to the issuance of a Certificate of Authority.

B. The examination shall be based on, but not limited to, the following:

1. The effectiveness of quality of care monitoring;
2. A medical referral system which is both available and accessible;
3. Continuing education programs to upgrade the expertise of all professional and non-professional personnel; and
4. Other quality issues in relation to the number of Enrollees.

C. Complaints concerning the quality of care shall be investigated by the Department without prior notice to the HMO. Complaints determined to be substantiated may require a full survey of the HMO, which shall be unannounced.

D. Requirements concerning a statement of deficiencies cited on surveys and complaint investigations are as follows:

1. The Department shall provide the HMO with a written statement of the survey outcome;
2. If deficiencies are cited, a written plan of correction shall be returned to the Department within thirty (30) days of receipt of the written statement of deficiencies;
3. Deficiencies which represent an immediate health and safety concern to Enrollees shall be corrected in a time frame that is appropriate. A time frame will be established for each such deficiency, and in no case shall exceed thirty (30) days from the date of receipt of the written statement of deficiencies;
4. All other deficiencies shall be corrected within sixty (60) days of receipt of the written statement of deficiencies. Documentation for justification of a longer time frame shall be provided to the Director.

E. The department may impose disciplinary action in the following instances:

1. The HMO fails to develop an acceptable plan of correction for deficiencies within the time frame allowed;
2. The HMO fails to implement and complete its plan of correction within the time frame approved by the Department;
3. The HMO fails to notify the Department of changes in operation that would affect previous considerations for applications or amendments to the Certificate of Authority;
4. The HMO fails to provide the Department with required reports and other documents,

as requested; and

5. The HMO fails to pay fees or other expenses required by these Rules and Regulations.

F. Each affected HMO shall receive written notice of the Department's disciplinary action. A written response shall be made to the Department within ten (10) calendar days of receipt of the notice. The response may exercise the HMO's right of appeal of the Director's disciplinary action.

G. Any charge of noncompliance shall be removed after determination that the HMO has corrected the deficiency(ies) which prompted the request for disciplinary action.

SECTION XXII. SEVERABILITY.

If any provision of these Rules and Regulations, or the application thereof to any person or circumstances is held invalid, such invalidity shall not affect other provisions or applications of these Rules and Regulations which can give effect without the invalid provision or applications, and to this end the provisions hereto are declared to be severable.

SECTION XXIII. REPEAL.

All Regulations and parts of Rules and Regulations in conflict herewith are hereby repealed.

CERTIFICATION

This will certify that the foregoing Rules and Regulations for Health Maintenance Organizations in Arkansas were adopted by the Arkansas State Board of Health at a regular session of said Board held in Hot Springs, Arkansas on the 23rd day of July, 1998.

George Harper
Secretary, Arkansas State Board of Health
Acting Director, Arkansas Department of Health

Dated at Hot Springs, Arkansas, this 23rd day of July, 1998.

The foregoing Rules and Regulations, copy having been filed in by office, are hereby approved on this 26 day of August, 1998.

Mike Huckabee
Governor of the State of Arkansas